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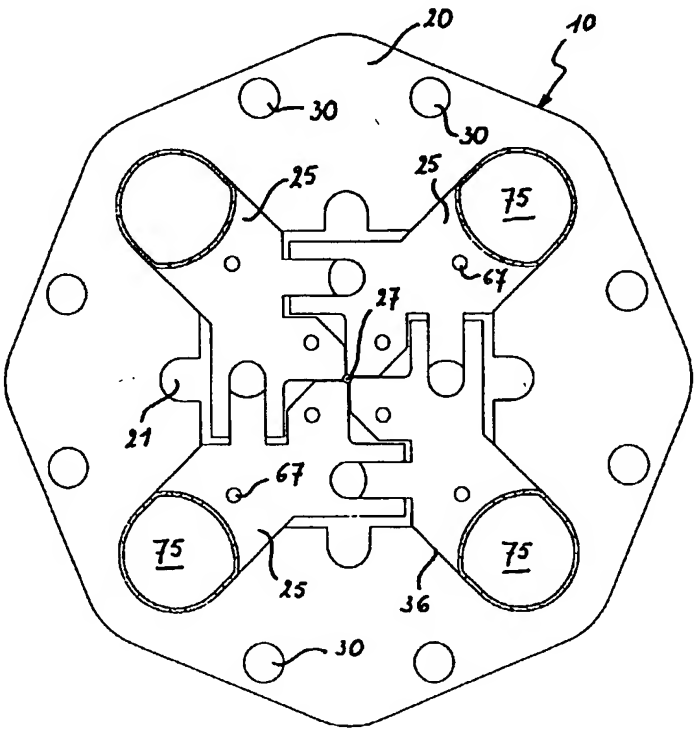
(54) Title: DEVICE FOR CRIMPING A STENT ONTO A CATHETER DELIVERY SYSTEM



(57) Abstract: A device for crimping a stent onto a catheter delivery system which comprises: a generally tubular channel having a longitudinal axis and having a circumferential wall formed by four spaced longitudinal elements; entrance means at one end of said generally tubular channel for allowing a delivery system to be inserted into said generally tubular channel and be positioned at a predetermined position relative thereto; pressure application means for forcing said four spaced longitudinal elements toward said longitudinal axis to compress and crimp said stent against said delivery system to form a unitary delivery system and stent assembly; and releasing means engaging said four elements for expanding said channel to allow said delivery system and stent assembly to be removed from said channel through said entrance means, wherein each longitudinal element as seen along the longitudinal axis of the tubular channel, is composed of a number of individual segments, each segment being movable by said pressure application means and said releasing means independently from each other segment within the same element.

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Device for crimping a stent onto a catheter delivery system

The invention relates to a device for crimping a stent onto a catheter delivery system which comprises :

- a generally tubular channel having a longitudinal axis and having a circumferential wall formed by four spaced longitudinal elements;
- entrance means at one end of said generally tubular channel for allowing a delivery system to be inserted into said generally tubular channel and to be positioned at a predetermined position relative thereto;
- pressure application means for forcing said four spaced longitudinal elements toward said longitudinal axis to compress and crimp said stent against said delivery system to form a unitary delivery system and stent assembly; and
- releasing means engaging said four elements for expanding said channel to allow said delivery system and stent assembly to be removed from said channel through said entrance means.

Such a device is known from US-A-5.672.169.

In this known device the four spaced longitudinal elements are moved back and forth in the direction of the longitudinal axis in order to compress the stent on the catheter delivery system by means of actuators including elastic rod means whereby each segment is moved as a whole. In this way the stent is compressed as one unit and the amount of compression of the stent is the same over its entire length.

In practice however it has been found that the compression of the stent needs to be varied as seen along the longitudinal axis. This is due to the fact that the catheter delivery system shows small irregularities along its length, as a result of e.g. wall thickness variations. If each element is moved as a whole this will result in additional deformation forces at the places where irregularities occur in the delivery system, e.g. on places where the catheter delivery system has a larger diameter. Such irregularities in the deformation of the stent may result in damage to the balloon material thus giving a lower possible inflation pressure and may result in non-adequate attachment of the stent to the balloon.
Both examples have negative impact on the safety of the implantation procedure.

It is therefor an object of the invention to provide a system according to the introductory part of the description, in which this and other disadvantages has been avoided.

This object is obtained by a device for crimping a stent onto a catheter delivery system which comprises :

- a generally tubular channel having a longitudinal axis and having a circumferential wall formed by four spaced longitudinal elements;
- entrance means at one end of said generally tubular channel for allowing a delivery system to be inserted into said generally tubular channel and be positioned at a predetermined position relative thereto;
- pressure application means for forcing said four spaced longitudinal elements toward said longitudinal axis to compress and crimp said stent against said delivery system to form a unitary delivery system and stent assembly; and
- releasing means engaging said four elements for expanding said channel to allow said delivery system and stent assembly to be removed from said channel through said entrance means, wherein each longitudinal element as seen along the longitudinal direction of the tubular channel, is composed of a number of individual segments, each segment being movable by said pressure application means and said releasing means independently from each other segment within the same element.

In this way it becomes possible to have an equal pressure applied to the stent in order to compress it around the catheter delivery system, whereas at the same time small irregularites on the surface conditions of the catheter delivery system are equallsed.

Preferably each longitudinal element is composed of the same number of segments, each segment having a plate-like shape with two parallel side walls, each side wall being in contact with the side wall of its neighbouring segment in the same element, the side walls being positioned perpendicularly to the longitudinal axis and the side walls of the segments with the same serial number in each element being positioned in the same plane.

In this way a compressing system is obtained having a number of four segments each time cooperating on one part of the catheter delivery system, thereby providing an adequate compression of the stent on that part.

In a preferred embodiment each segment has a curved surface edge directed towards the longitudinal axis of the tubular channel so that the edge of each segment engaging the stent is optimized in shaped.

Preferably the curved surface of each segment is limited by two stop edges, which are perpendicular with respect to each other, and in a closed position in which all segements are as close as possible to the longitudinal axis of the tubular channel, each stop edge abuts upon a stop edge of a segment of an adjacent element. In this way movement of the segment towards the longitudinal axis is stopped by engagement of the stop edges of two adjacent elements, thereby limiting the compression of the stent on the catheter delivery system.

In order to provide a controlled movement of the segments each segment is provided with guiding edges co-operating with guiding surfaces in a housing, the general guiding direction being under an angle of 45° with respect to the stop edges and directed towards the longitudinal axis of the tubular channel.

In order to obtain the best possible compression of the stent it is preferred that in the closed position the curved edges forms a circle.

In order to simplify production of the segments, so as to have the less possible number of different parts it is preferred to have identical segments. Thereby it is possible to have segments in which in the closed position, the stop edge of any segment is positioned in such a way that the longitudinal axis is lying in the extension of the stop edges or in which in the closed position, the stop edge of a segment is positioned in such a way that the longitudinal axis is not lying in the extension of the stop edges.

When using such a configuration, the border line between the adjacent stop edges of the segments in two adjacent elements and the curved edges becomes a straight line. As before reaching the complete compression of the stent there is space between the adjacent stop edges, the stent may be squeezed between the stop edges, and thereby be deformed, so that a useless catheter delivery system might be obtained.

In order to overcome this, different types of segments can be used with respect to the position of their stop edges in such a way that the sequence of the segments in each element is such that in the closed position the border line between the adjacent stop edges and the curved edge, is a broken line at each transition of one segment to the next segment in the same element.

In a preferred embodiment the segments are all identical and such that in the closed position, the stop edge of a segment is positioned in such a way that the longitudinal axis is not lying in the extension of the stop edges and all segments are identical and, each segment in an element is inversed with respect to its adjacent segment thereby forming a broken edge line between the adjacent stop edges and the curved edges.

In this way the squeezing of the stent can be avoided.

In order to improve the independent movement of the segments, distance elements are placed between the adjacent segments.

It is preferred that each segment is provided with means cooperating with the adjacent segments in the two adjacent elements, whereby a movement of a segment is transferred in a corresponding movement of its adjacent segments.

In this way it becomes possible to coordinate the movement of the different segments to such an extend that a uniform compression of the stent can be obtained.

Other advantages and characteristics will become clear from the following description, reference being made to the annexed drawings in which

Fig. 1	is a cross-section view of a device for crimping a stent onto a catheter delivery system according to the invention,
Fig. 2	is a partially exploded view of the core part of the system of Fig. 1, and
Fig. 3	is a top view of a segment used to form the core part shown in Fig. 2
Fig. 4A - 4B	are schematic representations of the core part of the systems before starting the crimping.
Fig. 5A - 5B	are schematic representations according to Figures 4A - 4B in an intermediate position, and
Fig. 6A - 6B	are schematic representations according to Figures. 4A - 4B in the most compressed position.

In Fig. 1 there is shown a device 10 for crimping a stent onto a catheter deliver system.

The device 10 comprises a housing 20, having a generally octogenal cross-section and provided with a longitudinal bore 21 having a cross-shaped cross-section for housing the moving parts of the compressing systems. Both ends of the housing 20 are closed by means of one or more removable end plates which provides support and access to the several parts to be described below.

The housing 20 is provided with a number of bores 30 e.g. eight in the embodiment shown, which are used to accommodate tie rods, by means of which the end plates can be fitted to the housing 20 and which at the same time increase the strength of the whole construction.

Whithin the cross-shaped bore 21 in the housing 20 there are four elements 25. As shown in Fig. 2. Each element 25 consists in fact of plate like segments 26 having two parallel flat side walls which are stacked on top of each other and together form each time one of four elements 25.

The segments 26 are positioned in such a way within the elements 25 that each time four segments within the four elements are exactly within the same plane, i.e. these side walls are aligned with respect to each other.

Each segment has a curved edge 40, directed towards a substantially cylindrical longitudinal channel 27 having a longitudinal axis, the four curved edges 40 of four coplanar segments 26 being capable to form together a closed circular edge, of a circle circumference.

The curved edge 40 of each segment 26 is limited by two stop edges 41, 42 which are positioned under an angle of 90° with respect ot each other, and which serve to engage corresponding stop edges 41, 42 of coplanar segments 25. Extending from the stop edge 41 and parallel to the stop edge 42 there is provided a substantially rectangular recess 43, which is limited by two longitudinal edges 44, 45 and a semi-circular edge 46. Edge 44 forms part of a rectangular notch 47, which is limited by edges 48, 49, edge 48 being parallel to edge 44 and edge 49 being perpendicular thereto. Edge 45 forms part of a rectangular notch 50, which is further limited by edges 51, 52, edge 51 being parallel to edge 45 and edge 52 being perpendicular thereto. The design is such that the notches 47, 50 extend with respect to the stop edge 41.

At the side of the stop edge 42, the segment 26 is provided with a substantially rectangular notch 53, formed by longitudinal edges 54, 55 and a top edge 56 have a concave curvature. The edges 54, 55 are parallel to stop edge 41 and therefor perpendicular with respect to stop edge 42. Edge 54 is part of a recess 57 which is further limited by edges 58, 59 and 60, edge 58 being perpendicular with respect to edge 57, edge 59 being parallel to edge 54 and edge 60 extending under an angle of e.g. 45° with respect to edge 59 and connecting the same to teh stop edge 42.

The width of the notch 53 is such that is equal to the width of the reces 43. Furthermore the design is made such that the concave edge 56 is almost aligned with the stop edge 42, whereas the length of the edge 54 is almost equal to the length of the edge 48.

Edge 55 is further limited by an edge 61 which is aligned with edge 58, thereby providing an edge 55 with the same length as edge 54.

Two edges 62, 63 are joined to the edge 51, and 61 respectively, the edges 62, 63 being parallel to each other and extending under an angle of 45° with respect to the main direction of the edges 51, 61. The contour of the segment 26 is mainly oriented in a direction perpendicular with respect to the edges 62, 63.

The segment 26 is further provided with two bores 65, 66 which are used to slide the segment 26 on rods 67, in order to stack a number of segments so as to obtain an element 25. preferably the diameter of the rods is slightly smaller than the diameter of the bores 65, 66 thereby providing some freedom of movement.

In the embodiment shown in the Figure 1 and 2 all segments are identical and the whole of the crimping device is obtained by sliding each time four coplanar segments 26 over the rods 67 the four coplanar segments being positioned with respect to each other as shown in Figure 1 and 2. This means that the notch 53 of each segment 26 is fitting into the recess of its adjacent coplanar segment 26. As the distance between the edges 62, 63 is equal to the width of the cross-arms of the cross-shaped bore, each segment 26 is able to slide in these cross-arms which serve as a guide therefor.

In this way a system has been obtained in which each coplanar set of segments 26 is able to move through and fro in the direction of the central axis 27, thereby guided by the edges 62, 63 along the respective cross-arms, which movement is possible because of the clearance

between the rod 67 and the bore 66. At the same time the through and fro movement of each segment is coordinated with the movement of the other coplanar segments because of the coupling between the coplanar segments by means of the notches 53 and recesses 43. Otherwise the movement of each coplanar set of segments is completely independent of the movement of its adjacent coplanar set of segments. This independency of adjacent sets of coplanar segments is even improved by providing distance elements, such as distance rings 70 between adjacent segments of the same element.

In the embodiment shown, the movement of the segments 26 is obtained by means of inflatable hoses. In order to move the segments 26 in the direction of the central axis of the channel 27 four inflatable hoses 75 have been provided between the concave edges 64 of the segments 26 of each element 25 and the end portion of the cross-arms of the bore 21. In this way one hoses75 is present for each element 25, the four hoses 75 being connectable to the same source of pressurized air, and therefor being maintained under the same pressure. Because of the flexibility of the hoses, all segments 26 are pressed with the same force towards the central channel, but the movement of each coplanar set of segments is within defined limits, independent from the movement of its adjacent coplanar set of segments there allowing adjustment for small irregularities.

In order to move the segments away from the central axis 27, four inflotable hoses have been provide, each in each longitudinal space provided between the edges 46 of the recesses 43 of all segments of one element and between the edges 56 of the notches 53 of all segments of its adjacent element.

By inlating these hoses, while at the same time releasing the pressure in the hoses 75, it is possible to move the segments away from the central channel 27.

As explained above all segments are identical. In its most simple embodiment of the invention each curved edge 40 can be shaped as one fourth of a circle circumference. This means that after full movement of the four segments of each coplanar set of segments a full circle circumference is obtained around the central channel 27. If the diameter of the circle corresponds substantially to the diameter of the catheter delivery system inserted into the central channel 27 a good crimping of the stent can be obtained.

There are however two problems with such a design. On the first place the border line between the curved edges of two adjacent segments is a straigth line. This means that the stent after being positioned around the catheter delivery system, where the elements are all in their fully

rectracted position, the stent might be squeezed between two moving stop edges of segments of adjacent elements. This is especially true in that the stent is positioned with some freedom of movement around the catheter delivery system and is free to move to a more or less decentral position.

Another problem with this type of segments is that for each diameter of catheter delivery sytem a suitable segment must be used in order to have an optimized result. In fact the diameter of the circle circumference formed by the curved edges, must be almost equal to the end diameter of the stent around the catheter delivery device.

The first problem can be overcome by using a quarter part of a circle circumference for the curved edge 40 which is positioned in such a way with respect ot he stop edges 41, 42 that the angle between the edge 41, 42 and the curved edge 40 is different from 90°. This can be done because the movement fo the segment 26 is under an angle of 45° with respect to the edges 41, 42, so that after engagement of the stop edges 41, 42 a complete circle circumference is obtained.

If at the same time the orientation of the each four coplanar segment is inversed from each coplanar set to the adjacent coplaner set, the situation as shown in Figures 4A - 4D will be obtained.

In fig. 4A there is shown the starting position of the elements, this is the position in which a catheter delivery system with thereupon a stent can be positioned in the central channel 27.

In fig. 4B there is shown the relative position of a number of segments with their curved edge 40 and their stop edges 41, 42. In the view of Fig. 4A two adjacent segments of each element are shown. A first segment is shown comprising the stop edges 41a, 42a and the intermediate curved edge 40a and a second segment is shown comprisiong the stop edges 41b, 42b and the intermediate curved edge 40b. As becomes clear from fig. 4A there is partly an overlap between the curved edges 40a, 40b.

In fig. 5A - 5B the situation is shown in which after movement of the elements towards the central channel a position is reached in which the stop edge 41 is aligned with the stop edge 41 of the opposed segment of the same coplanar set of segments. The stop edges of adjacent segments of the coplanar set of segments do not touch in this situation, but there is still some distance to move before complete abutment of the stop edges. As becomes clear from Fig. 5A the central channel 27 has a substantial cylindrical configuration, which is not continuous, but in

view of the small thickness of the segment is be having as such. Moreover there is no continuous straight split between two adjacent elements, but a broken line as shown in Fig. 5B.

If the catheter delivery system and its stent used have a diameter smaller than the average diameter shown in Fig. 5A, there is no danger that the stent becomes squeezed between two adjacent elements. From this position on the stent may be compressed. The compression can be prosecuted until the position as shown in Fig. 6A and 6B has been reached in which there is complete abutment of the stop edges. As the central channel 27 remains substantially cylindrical during the transition from the situation shown in Fig. 5B up til the situation shown in Fig. 6A, it becomes possible to use catheter delivery systems having any diameter between the average diameter of the central channel 27 in Fig. 5A and the diameter of the central channel 27 in Fig. 6B.

By using a catheter delivery device having a diameter which is somewhat larger than the diameter of the central channel 27 of Fig. 6B, a pressure regulated compression of the stent on the catheter delivery device can be obtained.

In a special embodiment of the system according to the invention two devices are used in succession. In the first device the diameter of the central channel 27 as shown in Fig. B is slightly larger than the diameter of the catheter delivery system, so that the stent is smoothly compressed on the catheter delivery system, the deformation of the stent being restricted and defined by the ultimate diameter of the channel 27.

In the second and subsequent device an ultimate diameter of the central channel 27 as shown in Fig. 6B is used whcih is smaller than the diameter of the catheter delivery device, so that the deformation of the stent is governed by the force exerted by the pressure devices 75.

Claims

1. A device for crimping a stent onto a catheter delivery system which comprises :
   - a generally tubular channel having a longitudinal axis and having a circumferential wall formed by four spaced longitudinal elements;
   - entrance means at one end of said generally tubular channel for allowing a delivery system to be inserted into said generally tubular channel and be positioned at a predetermined position relative thereto;
   - pressure application means for forcing said four spaced longitudinal elements toward said longitudinal axis to compress and crimp said stent against said delivery system to form a unitary delivery system and stent assembly; and
   - releasing means engaging said four elements for expanding said channel to allow said delivery system and stent assembly to be removed from said channel through said entrance means, wherein each longitudinal element as seen along the longitudinal axis of the tubular channel, is composed of a number of individual segments, each segment being movable by said pressure application means and said releasing means independently from each other segment within the same element.

2. A device according claim 1, characterised in that each longitudinal element is composed of the same number of segments, in that each segment has a plate-like shape with two parallel side walls, each side wall being in contact with the side wall of its neighbouring segment in the same element, the side walls being positioned perpendicularly to the longitudinal axis and in that the side walls of the segments with the same serial number in each element being positioned in the same plane.

3. A device according to claim 1 or 2, characterised in that each segment has a curved edge directed towards the longitudinal axis of the tubular channel.

4. A device according to claim 3, characterised in that the curved edge of each segment is limited by the two stop edges, which are perpendicular with respect to each other, and in that in a closed position in which all segments are as close as possible to the longitudinal axis of the tubular channel, each stop edge abuts upon a stop edge of a edge of a segment of an adjacent element.

5. A device according to claim 4, characterised in that each segment is provided with guiding edges co-operating with guiding edges in a housing, the general guiding direction being under an angle of 45° with respect to the stop surfaces and directed towards the longitudinal axis of the tubular channel.

6. A divice according to claim 4 or 5, characterised in that in the closed position the curved surfaces forms a circle.

7. A device according to claim 6, characterised in that in the closed position, the stop edge of any segment is positioned in such a way that the longitudinal axis is lying in the extension of the stop edges.

8. A device according to claim 7, characterised in that in the closed position, the stop edges of a segment is positioned in such a way that the longitudinal axis is not lying in the extension of the stop edges.

9. A device according to claims 7 and 8, characterised in that the sequence of the segments in each element is such that in the closed position the border line between the adjacent stop edges and the curved edges, is a broken line at each transition of one segment to another segment within the same element.

10. A device according to claim 8, characterised in that all segments are identical and, each segment in an element is inversed with respect to its adjacent segment thereby forming a broken line of abutting contact surfaces.

11. A device according to any one fo the preceeding claims, characterised in that distance elements are placed between the adjacent segments.

12. A device according to any one of the preceeding claims, characterised in that each segment is provided with means cooperating with the adjacent segments in the two adjacent elements, whereby a movement of a segment is transferred in a corresponding movement of its adjacent segments.

13. A device according to any one of the claims 4 - 11 and claim 12, characterised in that each segment is provided with a cam comprising two guiding walls parrallel to one stop edge of the segment, and a recess comprising two guiding walls parallel to the other

stop edge of the segment, each cam cooperting with the recess of the adjacent segment in the adjacent element.

14. A device according to claim 13, characterised in that between the recess of the segment and the cooperating cam of a neighbouring segment resilient means are provided which means can generate a pressure to slide the cam in the direction out of the recess.

15. A device according to claim 14, characterised in that the resilient means are made of an inflatable hose.

16. A device acording to any one of the preceeding claims, characterised in that each block is provided with at least two bores, and rods are passing through said bores with some tolerances.

17. A device according to any one of the preceeding claims, characterised in that the pressure application means comprises a number of inflotable tubes, all tubes being subjected to the same pressure.

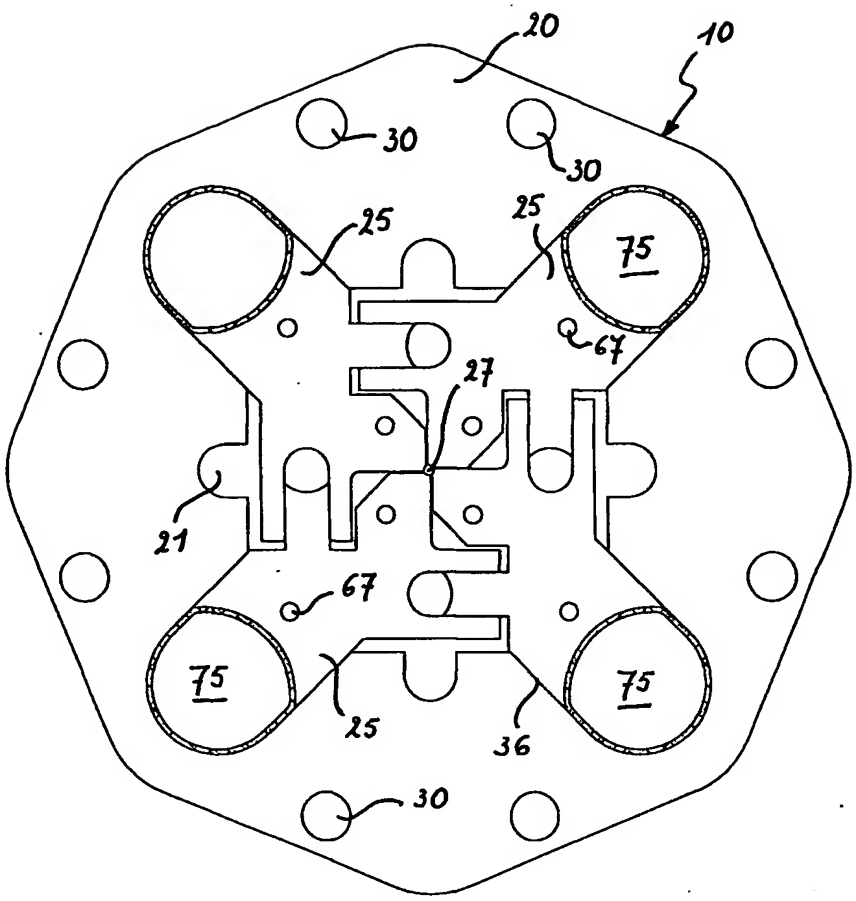

Fig. 1

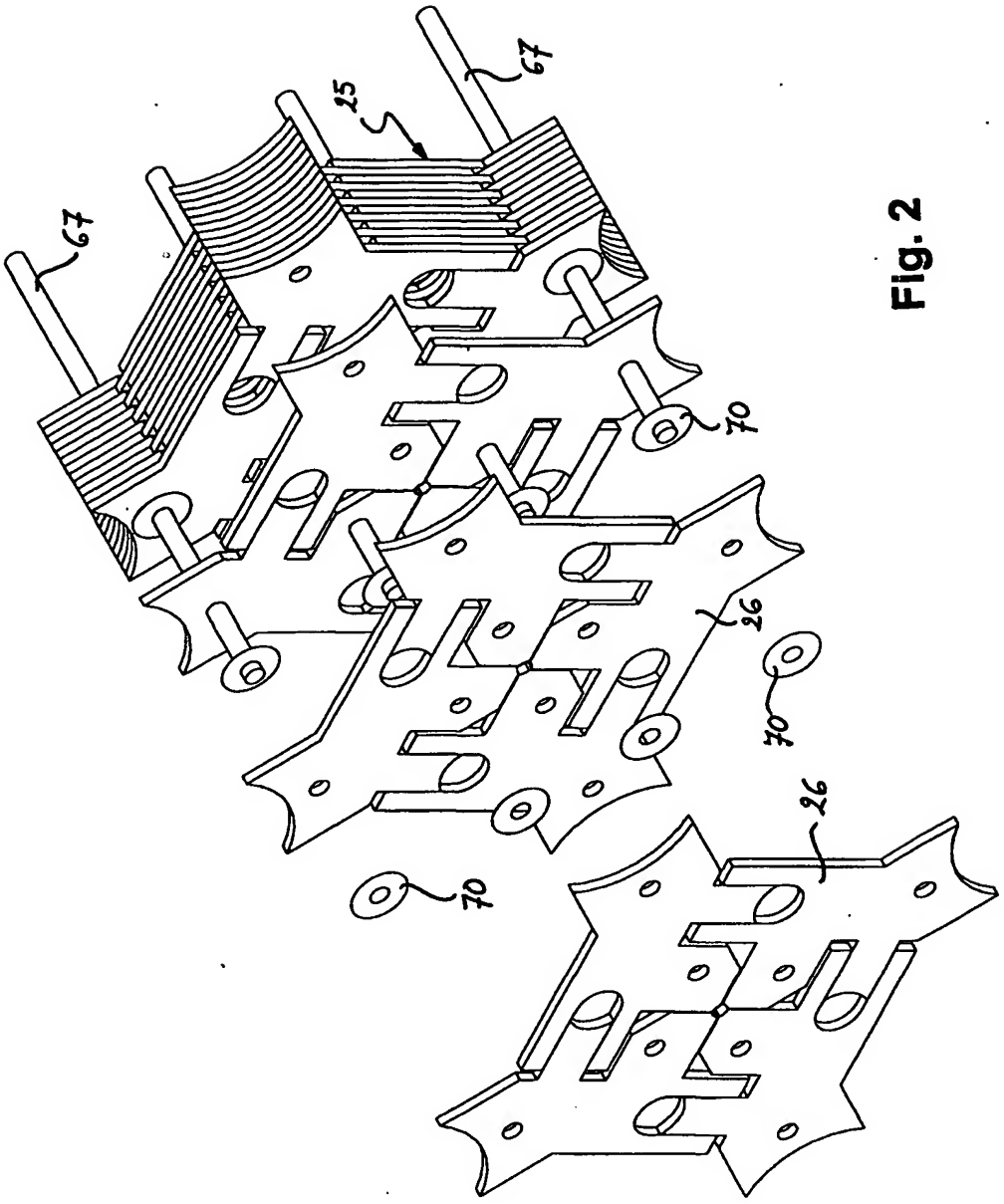

Fig. 2

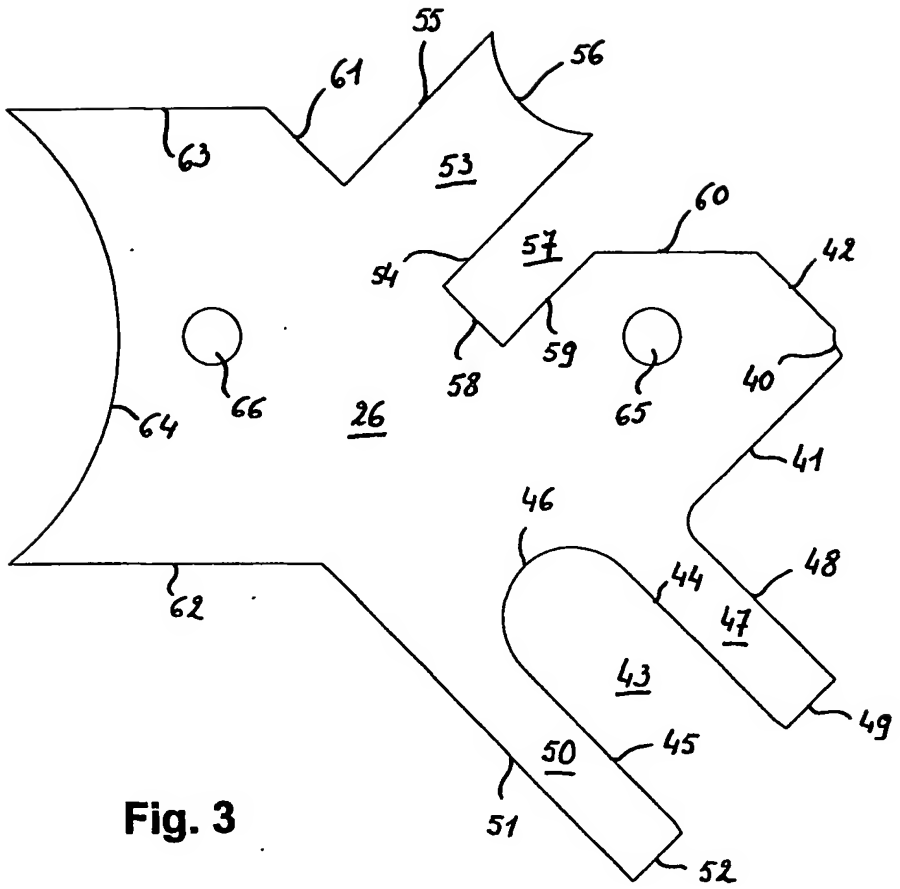
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Fig. 3

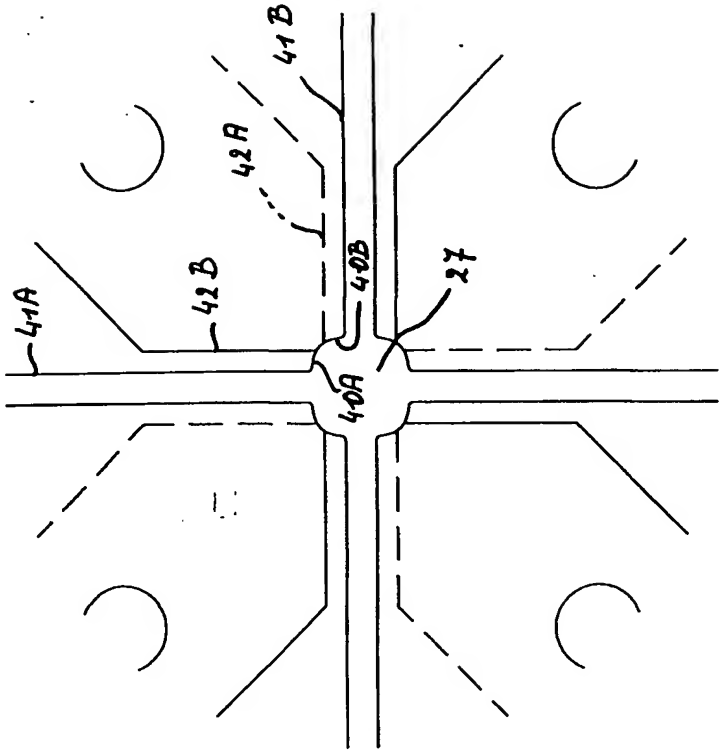

Fig. 4B

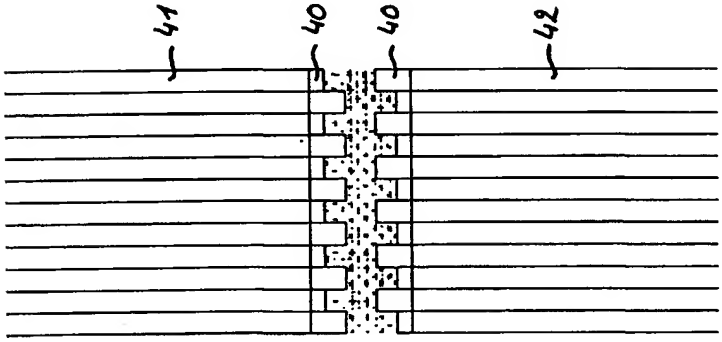

Fig. 4A

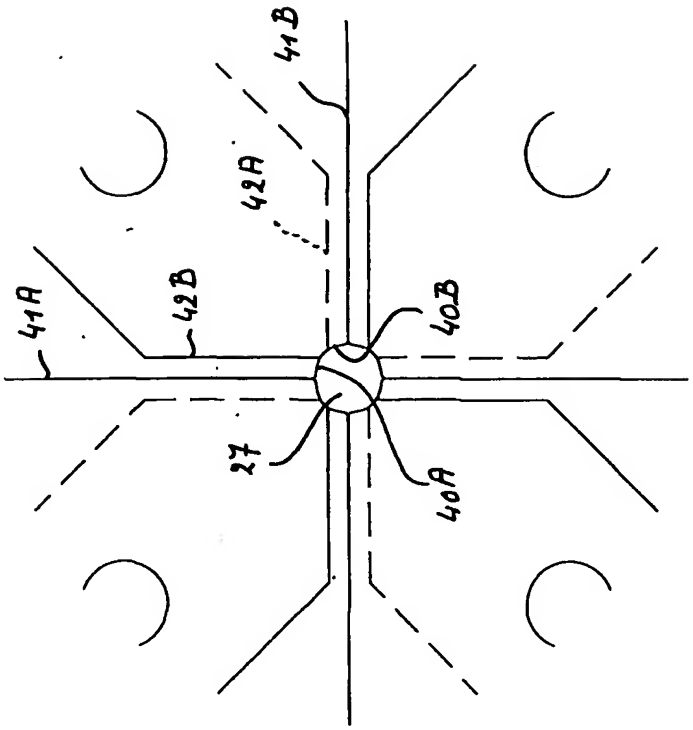

Fig. 5B

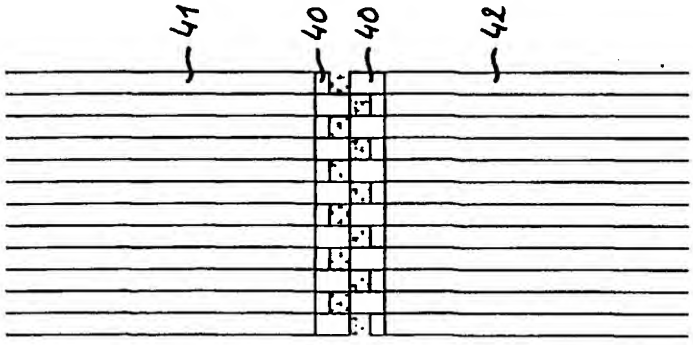

Fig. 5A

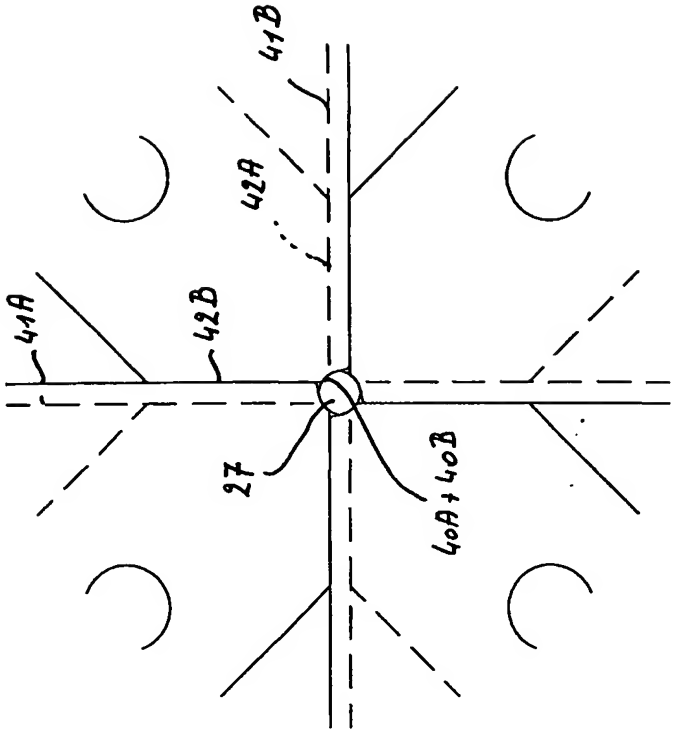

Fig. 6B

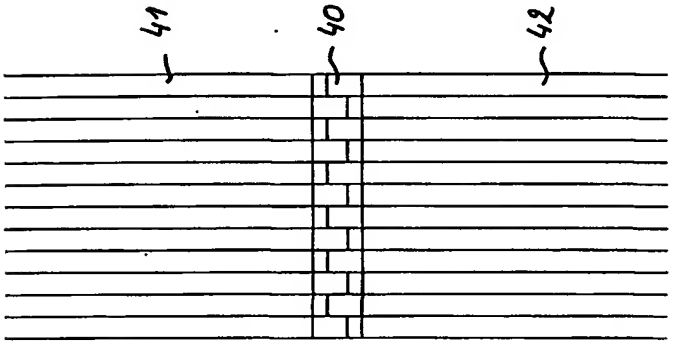

Fig. 6A

INTERNATIONAL SEARCH REPORT

Inl xnal Application No
PCT/EP 00/07695

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F B25B B21D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 951 540 A (VERBEEK MARCEL A E) 14 September 1999 (1999-09-14) column 6, line 9 - line 63; figures column 8, line 12 - line 24	1-10,12, 16,17
A	EP 1 018 320 A (MEDINOL LTD) 12 July 2000 (2000-07-12) paragraph '0021! - paragraph '0025!; figures 13-16	1-4,6
A	US 5 672 169 A (VERBEEK MARCEL A E) 30 September 1997 (1997-09-30) cited in the application column 4, line 66 -column 5, line 20; figures	1,3

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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